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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,108	07/18/2003	Ken-Shwo Dai	U 014726-8	4088
7590	12/19/2005			
Ladas & Parry 26 West 61st Street New York, NY 10023			EXAMINER SANG, HONG	
			ART UNIT	PAPER NUMBER
			1643	
DATE MAILED: 12/19/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/623,108	Applicant(s) DAI, KEN-SHWO	
	Examiner Hong Sang	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-29 and 32-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Dai

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, drawn to an isolated polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NOS. 2 and 4, and fragments thereof, classified in class 530, subclass 350.
 - II. Claims 4-11, drawn to an isolated nucleic acid comprising a nucleotide sequence selected from the group consisting of SEQ ID NOS. 1, 3, 5 and 7, and fragments thereof, an expression vector, a host cell, a method for producing an isolated polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NOS. 2 and 4, and fragments thereof classified in class 536, subclass 23.1.

If applicants elect this group for prosecution on the merits, applicants are further required to elect a single SEQ ID NO. from SEQ ID NOS. 1, 3, 5 and 7. This election should not be construed as an election of species. This is a restriction requirement. Each of the SEQ ID NOS. is a structurally and functionally distinct molecule that would require separate.
 - III. Claim 12, drawn to an antibody specifically binding to the polypeptide of claim 1, classified in class 530, subclass 387.1.

- IV. Claims 13-29, drawn to a method for diagnosing the disease associated with the deficiency of the SMAPK3 gene in a mammal, in particular cancers, which comprises detecting the nucleic acids of claim 4, classified in class 435, subclass 6.

If applicants elect this group for prosecution on the merits, applicants are further required to elect a single SEQ ID NO. from SEQ ID NO. 1, 3, 5 and 7. This election should not be construed as an election of species. This is a restriction requirement. Each of the SEQ ID NOS. is a structurally and functionally distinct molecule that would require separate search.

- V. Claims 31-34, drawn to a method for diagnosing the disease associated with the deficiency of the SMAPK3 gene in a mammal, in particular cancers, which comprises detecting the polypeptide of claim 1, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

The polypeptide of group I and polynucleotide of group II are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. While a polypeptide of group I can be made using the

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polynucleotides of group II, the polypeptide can also be made by another and materially different process, such as by peptide synthesis or purification from the natural source. Further, the polynucleotide may be used for the processes other than the production of the protein, such as nucleic acid hybridization. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. Furthermore, a search of the nucleic acid molecules of group II would also requires an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group I. As such, it would be burdensome to search the inventions of groups I and II together.

The polypeptide of group I and the antibody of group III are patentably distinct for the following reasons:

While the inventions of both group I and group III are polypeptides, in this instance the polypeptide of group I is a single chain molecule that functions as an enzyme, whereas the polypeptide of group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group I and the antibody of group III are structurally distinct molecules; any relationship between a polypeptide of group I and an antibody of group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide. While the polypeptide of group I can be used to make antibodies of group III, the polypeptide of group I can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein

Furthermore, searching the inventions of group I and group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group III.

Furthermore, antibodies which bind to an epitope of a polypeptide of group I may be known even if a polypeptide of group I is novel. In addition, the technical literature search for the polypeptide of group I and the antibody of group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group II and the antibody of group III are patentably distinct for the following reasons. The antibody of group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group III which are composed of amino acids, and polynucleotides of group II, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group II will not encode an antibody of group III, and the antibody of group III cannot be encoded by a polynucleotide of group II. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group II and group III would impose a serious search burden since a search of the

polynucleotide of group II is would not be used to determine the patentability of an antibody of group III, and vice-versa.

Groups III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used to for treating a disease as opposed to being used for detecting polypeptide.

Searching the inventions of groups III and V together would impose serious search burden. The inventions of groups III and V have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the antibody and the method of detecting polypeptide using the antibody are not coextensive. The search for group V encompasses molecules which are claimed in terms of antibody-polypeptide complex, which are not solely required for the search of group III. The search for group V would require a text search for the method of detecting the polypeptide. Prior art which teaches an antibody would not necessarily be applicable to the method of detecting a polypeptide. Moreover, even if the antibody was known, the method of detecting a polypeptide using the product may be novel and unobvious in view of the preamble or active step.

Groups IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

The instant specification does not disclose that these methods would be used together.

The method for diagnosing the disease associated with the deficiency of the SMAPK3 gene in a mammal, in particular cancers, which comprises detecting the nucleic acids (group IV), and diagnosing the disease associated with the deficiency of the SMAPK3 gene in a mammal, in particular cancers, which comprises detecting the polypeptide (group V) are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material or comprises different methodological steps. For group IV, RT PCR is used, for group V, an antibody is used. Therefore, each method is divergent in materials and steps. For these reasons the Inventions of groups IV and V are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of groups IV and V have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of groups IV and V together.

Groups I and II and groups IV and V, group III and IV are unrelated because the product is not used or otherwise involved in the process.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145.

The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang
Art Unit 1643
Dec. 7, 2005



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER